Randomized Controlled Trial of Laparoscopic Primary Diaphragm Repair with Sutures Alone versus Sutures Reinforced with Mesh for Hiatus Hernia: A Long-Term Follow-Up

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To assess the recurrence of hiatal hernia five to ten years after repair using sutures versus sutures reinforced with non-absorbable mesh.

Ethical review	Approved WMO
Status	Pending
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Observational invasive

Summary

ID

NL-OMON53688

Source
ToetsingOnline

Brief title
PRIME Long-Term Follow-Up

Condition

- Abdominal hernias and other abdominal wall conditions
- Thoracic disorders (excl lung and pleura)
- Gastrointestinal therapeutic procedures

Synonym
hiatus hernia, mesh surgery

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Deels door het Rijnstate Vriendenfonds

Intervention

Keyword: cruraplasty, hiatal hernia, laparoscopy, mesh

Outcome measures

Primary outcome

Incidence of recurrent hiatus hernia (integrity of hiatal repair)

Secondary outcome

- Clinical recurrence of the hernia (symptomatology)

- Development of postoperative reflux disease

- Development of postoperative side-effects

- Overall satisfaction with surgical outcome

- Long-term complications

Study description

Background summary

Hiatal hernias are common and may cause a variety of symptoms such as heartburn, regurgitation and dysphagia which can influence patients* quality of life. Over the last decades, laparoscopic correction of hiatal hernia gradually replaced open repair. Initially, the standard approach to laparoscopic repair of hiatal hernias was hiatal repair with sutures to narrow the hole in the diaphragm through which the oesophagus enters the abdominal cavity. However, hiatal hernia repair with sutures alone is associated with a high recurrence rate. In many other fields of surgery mesh repair has become the standard method of practice. Especially in inguinal and cicatricial hernia repair, the use of mesh is associated with a reduction in hernia recurrence.

However, the use of mesh at the hiatus poses an additional risk of adhesion formation, postoperative dysphagia and esophageal erosion caused by mechanical

mesh irritation. Therefore the potential advantages of mesh repair may be offset by post-operative symptoms.

The PRIME trial demonstrated that there was no difference in postoperative dysphagia between the two groups one year after surgery. However, there was also no difference in recurrence of hiatal hernia demonstrated by barium swallow radiology or upper gastrointestinal endoscopy one year after surgery. Watson et al. demonstrated in their cohort that there was no difference in recurrence - radiologically and clinically - five years after suture versus non-absorbable mesh repair for large hiatal hernias.

Study objective

To assess the recurrence of hiatal hernia five to ten years after repair using sutures versus sutures reinforced with non-absorbable mesh.

Study design

Cross-sectional long term follow-up of a randomised controlled trial comparing two laparoscopic procedures for hiatal hernia repair.

Study burden and risks

The results of this study will tell us if there is a benefit or decreased benefit of using mesh in hiatal hernia surgery. This could impact the current standard of care. The risks for the participants of this study are low.
Subjection to X-ray radiation of modern CT scanning devices is considered safe, although it is of course a burden.
The patients will visit the hospital only once, to have the CT-scan.
Also they will be asked to fill out a relatively short questionnaire

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Participant of the original PRIME-trial
- Alive

Exclusion criteria

- No informed consent
- Additional hiatal hernia repair surgery during the follow-up period
- Pregnancy
- Patients that have stated they do not want to be approached for follow-up research
- Patients that do not want to know if they have a recurrence of the hiatal hernia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2023
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-04-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82840.100.22